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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/014,519	12/14/2001	Betty Wu	10255-028-999	3927

20582 7590 05/18/2004

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EXAMINER	
SINES, BRIAN J	
ART UNIT	**PAPER NUMBER**
1743	

DATE MAILED: 05/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/014,519	WU ET AL.	
	Examiner	Art Unit	
	Brian J. Sines	1743	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-38* is/are pending in the application.

4a) Of the above claim(s) *38* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-29 and 32-37* is/are rejected.

7)☒ Claim(s) *30 and 31* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Claim 38 is withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the response submitted 2/6/2004.

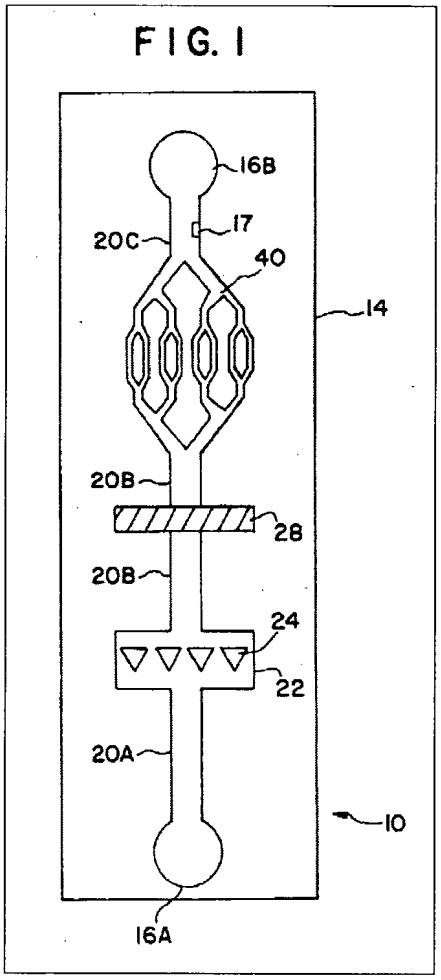
Claim Rejections - 35 USC § 102

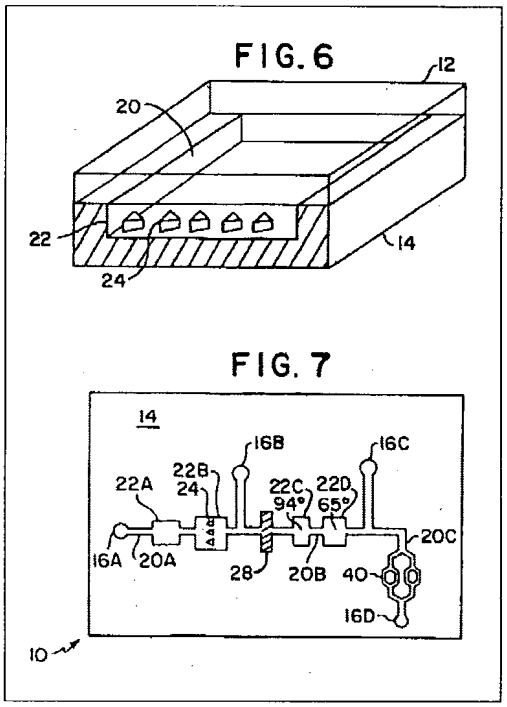
The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2, 6, 12, 15, 27, 33 and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Wilding et al. (U.S. Pat. No. 5,635,358 A). Regarding claims 1, 12 and 15, Wilding et al. teach an apparatus comprising: a lysing zone (cell handling region 22) configured to receive a cell-containing microdroplet; a positioning element (e.g., channel 20A) to position the cell-containing microdroplet in a lysing position with respect to the lysing zone; and a lysing mechanism (cell membrane piercing protrusion 24) to release intracellular material from cells contained within the lysing zone (see col. 6, lines 30 – 49; figures 1, 6 & 7). Regarding claims 2 and 34, Wilding et al. teach that the samples being analyzed are cell-containing liquid samples, such as for immunoassays and enzymatic assays (see col. 7, lines 1 – 14). Regarding claim 6, Wilding et al. further teach a positioning element (channel 20B) disposed downstream of the lysing zone (22) (see figure 1). Regarding claims 27 and 33, regarding process or method claims,

a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP § 2112.02).





Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

1. Claims 3 – 5, 32, 35 and 36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. in view of Tai et al. (U.S. Pat. No. 6,534,295 B2). Regarding claims 3, 4, 32, 35 and 36, Wilding et al. do not specifically teach the incorporation of an electrical field-based cell lysing mechanism within the microfluidic apparatus or a method step employing the use of such a lysing mechanism. However, Tai et al. do teach a micromachined cell lysis device based upon the application of pulsed electric fields (see col. 2, lines 31 – 67). Both of the cell lysing mechanisms disclosed by Wilding et al. and Tai et al. are notoriously well known in the art for being utilized for the same intended purpose, for the lysis of cell-containing samples within microfluidic devices. Hence, these cell lysis mechanisms are considered functional equivalents clearly recognized in the prior art (see MPEP 2144.06). Therefore, a person of ordinary skill in the art would have recognized the suitability of using an electrode-based cell lysis device within a microfluidic apparatus for the same intended purpose of facilitating cell lysis (see MPEP § 2144.07). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, the Courts have held that the

prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the teachings of Tai et al. regarding the use of a micromachined electrical field-based cell lysis device with the Wilding et al. microfluidic apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to provide a micromachined electric field-based cell lysing mechanism, as taught by Tai et al., with the Wilding et al. microfluidic apparatus in order to facilitate effective cell lysing and subsequent analysis. Regarding claim 5, Wilding et al. teach the use of pumps for effecting fluid transfer through the microfluidic device via fluid or gas pressure (see col. 8, lines 46 – 66; col. 9, lines 6 – 23).

2. Claims 7 – 11, 28 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. in view of Burdon et al. (U.S. Pat. No. 6,572,830 B1). Regarding claims 7 – 9, 28 and 29, Wilding et al. do not specifically teach the incorporation of a feature or method step which facilitates fluid flow control by increasing surface tension, such as a hydrophobic surface. Wilding et al. do teach the incorporation of valves within the apparatus for enabling flow control (see col. 9, lines 54 – 65). Burdon et al. do teach the incorporation of hydrophobic regions, such as for capillary stop structures, within the disclosed microfluidic apparatus, which provides for fluid flow control within the apparatus (see col. 28, lines 51 – 67; col. 29, lines 1 – 66). Both of these flow control mechanisms disclosed by Wilding et al. and Burdon et al. are notoriously well known in the art for being utilized for the same intended purpose, for the control of fluid flow within microfluidic devices. Hence, these fluid flow mechanisms and structures

are considered functional equivalents clearly recognized in the prior art (see MPEP 2144.06). Therefore, a person of ordinary skill in the art would have recognized the suitability of using a hydrophobic structure within a microfluidic apparatus for the same intended purpose of facilitating effective fluid flow control (see MPEP § 2144.07). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). As a result, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the teachings of Burdon et al. regarding the use of hydrophobic structures within the Wilding et al. microfluidic apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to provide the features recited in claims 7 – 9 with the microfluidic apparatus of Wilding et al. in order to facilitate effective fluid flow control.

Regarding claims 10 and 11, Wilding et al. do not specifically teach a change in the size or dimensions of a positioning element or channel structure. However, Burdon et al. do teach the use of fluid flow control structures, which incorporate changes in channel size (see col. 28, lines 51 – 66; col. 29, lines 1 – 13). The structures for fluid flow control disclosed by Wilding et al., such as valves, and the structures disclosed by Burdon et al. are regarded as functional equivalents recognized in the prior art (see MPEP 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not

necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Therefore, it would have been obvious to incorporate the structural features as recited in claims 10 and 11 with the Wilding et al. microfluidic apparatus to provide effective fluid flow control.

3. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. in view of Anderson et al. (U.S. Pat. No. 6,326,211 B1). Regarding claim 13, Wilding et al. are silent to the specific teaching of incorporating a vent within the microfluidic apparatus. Wilding et al. do teach the desirability of incorporating structures within the apparatus which enable mixing of the sample fluid with reagents to occur, such as with PCR reagents for subsequent analysis (see col. 10, lines 44 – 62). Anderson et al. do teach the incorporation of a vent structure within a microfluidic apparatus to facilitate sample fluid mixing (see col. 3, lines 46 – 56; col. 30, lines 9 – 21; figure 12b). Anderson et al. also teach the desirability of incorporating vent structures comprising hydrophobic plugs or membranes to enable the degassing or debubbling of sample fluids, since entrained bubbles may interfere with fluid flow and result in the production of irregular data (see col. 29, line 64 – col. 30, line 8). Hence, a person of ordinary skill in the art would have recognized the suitability of incorporating a vent structure, as taught by Anderson et al., with the microfluidic apparatus of Wilding et al., for the same intended purpose of enabling sample fluid mixing and degassing (see MPEP § 2144.07). In addition, the Courts have held that the prior art can be modified or combined to

reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Consequently, as evidenced by Anderson et al., a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating a vent structure with the Wilding et al. microfluidic apparatus in order to facilitate sample fluid mixing within the apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a vent structure, as taught by Anderson et al., with the microfluidic apparatus of Wilding et al., in order to facilitate effective sample fluid mixing and processing. The applicant is advised that although the function attributed to the incorporation of the vent structure may not be the same as that intended by the applicant (i.e, sample fluid mixing as opposed to fluid movement inhibition as recited in the claim), the resulting structure manifested in the claim language appears to be taught by the prior art. The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114). Regarding claim 14, Wilding et al. do teach the incorporation of valves within the apparatus to facilitate fluid flow control (see col. 10, lines 10 – 62). Anderson et al. further teach the incorporation of valves to control fluid flow within the apparatus as well (see col. 30, lines 9 – 65).

4. Claims 16, 17, 20 – 22, 24 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. in view of Brody (U.S. Pat. No. 5,726,404 A). Regarding claims 16, 20 – 22, 24 and 37, Wilding et al. teach an apparatus comprising: a silicon substrate (14) microfabricated with a mesoscale flow channel (20); a lysing zone (cell handling region 22) configured to receive a cell-containing microdroplet; a positioning element (e.g., channel 20A) to position the cell-containing microdroplet in a lysing position with respect to the lysing zone; and a lysing mechanism (cell membrane piercing protrusion 24) to release intracellular material from cells contained within the lysing zone (see col. 6, lines 30 – 49; figures 1, 6 & 7). Wilding et al. do not specifically teach the incorporation of a gas actuator. Wilding et al. do teach the incorporation of pumps for facilitating fluid movement within the apparatus (see col. 8, lines 52 – 66). Gas actuated fluid flow control systems are well known in the art, as evidenced by Brody (see col. 4, lines 32 – 67; col. 6, lines 57 – 60). Hence, these fluid flow mechanisms are considered functional equivalents recognized in the prior art (see MPEP 2144.06). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, a person of ordinary skill in the art would have recognized the suitability of using a gas actuated mechanism within a microfluidic apparatus for the same intended purpose of facilitating sample fluid flow within the apparatus (see MPEP § 2144.07). Therefore, it would have been obvious to a person of ordinary skill in the art to provide a gas actuated pumping mechanism to facilitate sample fluid movement, as taught by Brody, with the Wilding et al. microfluidic apparatus, in order to facilitate effective sample fluid transfer and processing within the apparatus. Regarding claim 17, Wilding et al. teach that the

samples being analyzed are cell-containing liquid samples, such as for immunoassays and enzymatic assays (see col. 7, lines 1 – 14). Regarding claim 22, the Courts have held that the use of a one-piece, integrated construction instead of the structure disclosed in the prior art would have been within the ambit of a person of ordinary skill in the art. See *In re Larson*, 340 F.2d 965, 968, 144 USPQ 347, 349 (CCPA 1965). Therefore, it would have been obvious to a person of ordinary skill in the art to integrate a lysing zone and a gas actuation device within the substrate of the microfluidic apparatus.

5. Claims 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. and Brody, as applied to claims 16, 20 – 22, 24 and 37 above, and further in view of Tai et al. Wilding et al. do not specifically teach the incorporation of an electrical field-based cell lysing mechanism within the microfluidic apparatus. However, Tai et al. do teach a micromachined cell lysis device based upon the application of pulsed electric fields (see col. 2, lines 31 – 67). Both of the cell lysing mechanisms disclosed by Wilding et al. and Tai et al. are notoriously well known in the art for being utilized for the same intended purpose, for the lysis of cell-containing samples within microfluidic devices. Hence, these cell lysis mechanisms are considered functional equivalents clearly recognized in the prior art (see MPEP 2144.06). Therefore, a person of ordinary skill in the art would have recognized the suitability of using an electrode-based cell lysis device within a microfluidic apparatus for the same intended purpose of facilitating cell lysis (see MPEP § 2144.07). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima*

facie obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Consequently, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the teachings of Tai et al. regarding the use of a micromachined electrical field-based cell lysis device with the microfluidic apparatus taught by Wilding et al. and Brody. Therefore, it would have been obvious to a person of ordinary skill in the art to provide a micromachined electric field-based cell lysing mechanism, as taught by Tai et al., with the microfluidic apparatus in order to facilitate effective cell lysing and subsequent analysis. Regarding claim 19, this claim recites an intended use or process limitation, which does not further delineate the structure of the claimed apparatus from that of the prior art. Since this claim is drawn to an apparatus statutory class of invention, it is the structural limitations of the apparatus, as recited in the claim, which are considered in determining the patentability of the apparatus itself. These recited process or use limitations are accorded no patentable weight to an apparatus. Process limitations do not add patentablility to a structure, which is not distinguished from the prior art. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967); and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

6. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. in view of Brody, as applied to claims 16, 20 – 22, 24 and 37 above, and further in view of Brudon et al. Wilding et al. do not specifically teach the incorporation of a feature which

facilitates fluid flow control by increasing surface tension, such as a hydrophobic surface. Wilding et al. do teach the incorporation of valves within the apparatus for enabling flow control (see col. 9, lines 54 – 65). Burdon et al. do teach the incorporation of hydrophobic regions, such as for capillary stop structures, within the disclosed microfluidic apparatus, which provides for fluid flow control within the apparatus (see col. 28, lines 51 – 67; col. 29, lines 1 – 66). Both of these flow control mechanisms disclosed by Wilding et al. and Burdon et al. are notoriously well known in the art for being utilized for the same intended purpose, for the control of fluid flow within microfluidic devices. Hence, these fluid flow mechanisms and structures are considered functional equivalents clearly recognized in the prior art (see MPEP 2144.06). Therefore, a person of ordinary skill in the art would have recognized the suitability of using a hydrophobic structure within a microfluidic apparatus for the same intended purpose of facilitating effective fluid flow control (see MPEP § 2144.07). The Courts have held that an express suggestion to substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). As a result, a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating the teachings of Burdon et al. regarding the use of hydrophobic structures within the Wilding et al. microfluidic apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to provide the features recited in claim 25 with the

microfluidic apparatus of Wilding et al. and Brody in order to facilitate effective fluid flow control.

7. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. in view of Brody, as applied to claims 16, 20 – 22, 24 and 37 above, and further in view of Anderson et al. (U.S. Pat. No. 6,326,211 B1). Wilding et al. are silent to the specific teaching of incorporating a vent within the microfluidic apparatus. Wilding et al. do teach the desirability of incorporating structures within the apparatus which enable mixing of the sample fluid with reagents to occur, such as with PCR reagents for subsequent analysis (see col. 10, lines 44 – 62). Anderson et al. do teach the incorporation of a vent structure within a microfluidic apparatus to facilitate sample fluid mixing (see col. 3, lines 46 – 56; col. 30, lines 9 – 21; figure 12b). Anderson et al. also teach the desirability of incorporating vent structures comprising hydrophobic plugs or membranes to enable the degassing or debubbling of sample fluids, since entrained bubbles may interfere with fluid flow and result in the production of irregular data (see col. 29, line 64 – col. 30, line 8). Hence, a person of ordinary skill in the art would have recognized the suitability of incorporating a vent structure, as taught by Anderson et al., with the microfluidic apparatus of Wilding et al., for the same intended purpose of enabling sample fluid mixing and degassing (see MPEP § 2144.07). In addition, the Courts have held that the prior art can be modified or combined to reject claims as *prima facie* obvious as long as there is a reasonable expectation of success. See *In re Merck & Co., Inc.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986) (see MPEP § 2143.02). Consequently, as evidenced by Anderson et al., a person of ordinary skill in the art would accordingly have had a reasonable expectation of success of incorporating a vent structure with the Wilding et al. microfluidic apparatus in order

to facilitate sample fluid mixing within the apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a vent structure, as taught by Anderson et al., with the microfluidic apparatus of Wilding et al., in order to facilitate effective sample fluid mixing and processing. The applicant is advised that although the function attributed to the incorporation of the vent structure may not be the same as that intended by the applicant (i.e, sample fluid mixing as opposed to fluid movement inhibition as recited in the claim), the resulting structure manifested in the claim language appears to be taught by the prior art. The Courts have held that the manner of operating an apparatus does not differentiate an apparatus claim from the prior art, if the prior art teaches all of the structural limitations of the claim. See *Ex Parte Masham*, 2 USPQ2d 1647 (BPAI 1987). Furthermore, the Courts have held that apparatus claims must be structurally distinguishable from the prior art in terms of structure, not function. See *In re Danley*, 120 USPQ 528, 531 (CCPA 1959); and *Hewlett-Packard Co. V. Bausch and Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (see MPEP § 2114).

8. Claim 23 is rejected under 35 U.S.C. 103(a) as being unpatentable over Wilding et al. in view of Brody, as applied to claims 16, 20 – 22, 24 and 37 above, and further in view of Anderson et al. (U.S. Pat. No. 6,197,595 B1). Neither Wilding et al. or Brody specifically teach the incorporation of a thermopneumatic pumping mechanism. Wilding et al. do teach the incorporation of pumps for facilitating fluid movement within the apparatus (see col. 8, lines 52 – 66). Anderson et al. do teach the use of thermopneumatic pumps comprising a heat source or element with a microfluidic apparatus (see col. 29, lines 14 – 36). Hence, these fluid pumping mechanisms are considered functional equivalents clearly recognized in the prior art (see MPEP 2144.06). The Courts have held that an express suggestion to substitute one equivalent

component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Furthermore, a person of ordinary skill in the art would have recognized the suitability of incorporating a thermopneumatic pumping mechanism within a microfluidic apparatus for the same intended purpose of facilitating sample fluid flow within the apparatus (see MPEP § 2144.07). Therefore, it would have been obvious to a person of ordinary skill in the art to provide a thermopneumatic pumping mechanism to facilitate sample fluid movement, as taught by Anderson, with the microfluidic apparatus, as taught by Wilding et al. in view of Brody, in order to facilitate effective sample fluid transfer and processing within the apparatus.

Allowable Subject Matter

Claims 30 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

The following is a statement of reasons for the indication of allowable subject matter: The cited prior art neither teach or fairly suggest a positioning step which comprises increasing a radius of curvature of the sample fluid microdroplet. The cited prior art neithert teach or fairly suggest a positioning step which comprises substantially equalizing a gas pressure upstream of the microdroplet with a gas pressure downstream of the microdroplet.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Briscoe et al. (US 6,544,734) teach a microfluidic DNA analysis system and method.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11:30 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).